

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : John H. Stevens
Serial No. : 10/047581 Art Unit : 3738
Filed : October 23, 2001 Examiner : C.D. Prone
Title : ENDOVASCULAR AORTIC VALVE REPLACEMENT

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APPEAL BRIEF UNDER 37 C.F.R. §41.37

Dear Sir:

This Appeal Brief is filed in response to the Final Rejection mailed November 19, 2009.

This Brief contains these items under the following headings, and in the order set forth below (37 CFR 1.192(c)):

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1. **Real Party In Interest:**

The real party in interest for this patent application is Ethicon, Inc., U.S. Route 22, Somerville, NJ 08876.

2. **Related Appeals and Interferences:**

There are no related appeals or interferences known to Appellant, the Appellant's legal representative, or the Assignee that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

3. **Status of Claims:**

Claims 15-20, 23, 25-32 and 42-44 stand as finally rejected and are presently appealed.

4. **Status of Amendments:**

No amendments have been filed after the final rejection of November 19, 2009.

5. **Summary of Claimed Subject Matter:**

The present invention, as claimed by independent Claim 1, is directed to a valve for implantation at a desired location within a mammal, comprising:

- a flexible sleeve having a proximal end, a distal end and an outside surface;
- at least one cusp secured to the sleeve and configured to permit blood flow through the at least one cusp in a single direction;
- at least one ring attached to the outside surface at only the proximal end of the sleeve, the at least one ring being attached to a portion of the sleeve that is not everted, wherein the ring is expandable from a first diameter to a larger, second diameter ; and
- at least one fastener connected to the at least one ring, the at least one fastener extending in a direction radially outward with respect to the sleeve and including at least one leg.

Support for this claim may generally be found on page 16, line 13 to page 17, line 2, of the Specification and in Figs. 9, 10, 11, and 13-15 of the Specification.

6. **Grounds of Rejection to be Reviewed on Appeal:**

Whether claims 15-20, 23, 25-32 and 42-44 are unpatentable under 35 U.S.C. 103(a) over US 5,824,064 (Taheri) in view of US 4,056,854 (Boretos).

7. **Argument:**

Claims 15-20, 23, 25-32 and 42-44 are patentable and not obvious under 35 U.S.C. 103(a) over US 5,824,064 (Taheri) in view of US 4,056,854 (Boretos).

A claimed invention is unpatentable if the differences between it and the prior art “are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art.” 35 U.S.C. § 103(a) (Supp. 1998); see *Graham v. John Deere Co.*, 383 U.S. 1, 14, 148 USPQ 459, 465 (1966). The ultimate determination of whether an invention is or is not obvious is a legal conclusion based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness. See *Graham*, 383 U.S. at 17-18, 148 USPQ at 467; *Miles Labs, Inc., Inc. v. Shandon Inc.*, 997 F.2d 870, 877, 27 USPQ2d 1123, 1128 (Fed. Cir.1993).

Turning to the prior art references that form the basis of the obviousness rejection, the Examiner cites Taheri as the primary reference. The Examiner refers to Figs. 2A and 2B which depict valve 23 comprising prosthesis (ring) 22 and frame 21 sewn into or onto ring 22. Fig. 2A is said to describe the structure in the closed position and Fig. 2B shows the device in the open position. The Examiner acknowledges that Taheri does not disclose that the ring 22 of Figs. 2A and 2B is expandable from a smaller diameter to a larger diameter. To overcome the deficiency of Taheri, the Examiner cites Boretos for teaching “use of an aortic heart valve comprising a base ring that is expandable in the same field of endeavor for the purpose of providing an implant that can be delivered to the implant site in a compact configuration, but expanded to the desired size at the implant site”. Based on the foregoing disclosure, the Examiner concludes that it would have been obvious to one having ordinary skill in the art at the time of the invention

was made to combine the expandable ring of Boretos with the implant of Taheri in order to provide an expandable implant with a smaller delivery configuration.

Appellant submits that the Examiner's rejection is impermissible at least on two (2) grounds. Firstly, the Examiner's rejection fails to recite a *prima facie* case of obviousness since there is failure to recite any feature of Taheri or Boretos that describes the claimed feature of "at least one fastener connected to the at least one ring, the at least one fastener extending in a direction radially outward with respect to the sleeve and **including at least one leg.**" The rejection and disclosure of both Taheri and Boretos fail to recite the fastener "**having at least one leg**" and it is unclear how the combination results in the claimed invention. On this ground alone, the rejection should be reversed.

Secondly, even if one were to ignore the lack of an articulated argument that the references cite the claimed fastener, it is not apparent from the Examiner's rejection how the combination of Taheri and Boretos would provide an operable device. That is to say, it is unclear how the device of Taheri would be made to expand from a smaller diameter to a larger diameter and how the unnumbered spikes on ring 22 of Taheri would allow placement in a desired location. If Fig. 2A represents the open position of the device and Fig. 2B represents the closed position of the device, how is the device advanced to the desired implant location without interference of the unnumbered spikes of ring 22? It does not appear that the unnumbered spikes on ring 22 are retractable. Thus, Appellant submits that the relied upon combination is inoperable and Examiner's obviousness rejection be reversed.

Thus, Appellant submits that the Examiner rejection must be reversed as it appears that the Examiner only arrived at his rejection based on the Appellant's own disclosure and as such has impermissibly reconstructed the claimed invention through hindsight.

Therefore, Appellant submits that the claimed valve is non-obvious and respectfully request the Board to reverse this rejection.

Conclusion:

For the reasons discussed above, Appellant maintains that the Examiner's final rejection of claims 15-20, 23, 25-32 and 42-44 as being unpatentably obvious should be reversed.

Respectfully submitted,

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8. CLAIMS APPENDIX

1-14. (Cancelled)

15. (Appealed) A valve for implantation at a desired location within a mammal, comprising:

 a flexible sleeve having a proximal end, a distal end and an outside surface;

 at least one cusp secured to the sleeve and configured to permit blood flow through the at least one cusp in a single direction;

 at least one ring attached to the outside surface at only the proximal end of the sleeve, the at least one ring being attached to a portion of the sleeve that is not everted, wherein the ring is expandable from a first diameter to a larger, second diameter; and

 at least one fastener connected to the at least one ring, the at least one fastener extending in a direction radially outward with respect to the sleeve and including at least one leg.

16. (Appealed) The valve of claim 15, wherein the at least one ring has a height that is less than the distance measured from the proximal end of the sleeve to the distal end of the sleeve.

17. (Appealed) The valve of claim 16, wherein the at least one cusp comprises three cusps attached to the sleeve, the three cusps being configured to open to permit blood to flow through the distal end when subjected to blood flow through the sleeve from the proximal end to the distal end.

18. (Appealed) The valve of claim 17, wherein the three cusps are configured to close to prevent blood flow through the sleeve from the distal end to the proximal end.

19. (Appealed) The valve of claim 17, wherein the valve is configured to have an open position that permits blood to flow through the distal end when blood flows through the

sleeve from the proximal end to the distal end and a closed position to prevent blood from flowing from the distal end to the proximal end of the sleeve.

20. (Appealed) The valve of claim 19, wherein each of the three cusps has at least one side and each of the three cusps are configured to mate along the at least one side with a side of a cusp located adjacent to each of the three cusps when the valve is in the closed position.

21. (Cancelled)

22. (Cancelled)

23. (Appealed) The valve of claim 15, wherein the ring is compressible.

24. (Cancelled)

25. (Appealed) The valve of claim 15, wherein the at least one fastener is for attaching at least the sleeve at a desired location.

26. (Appealed) The valve of claim 25, wherein the at least one fastener comprise a series of legs arranged circumferentially about the ring.

27. (Appealed) The valve of claim 25, wherein the ring has a longitudinal axis and the at least one fastener comprises at least one mounting pin attached to the ring, the mounting pin having two ends offset from one another in the longitudinal direction.

28. (Appealed) The valve of claim 27, wherein the two ends of the at least one mounting pin extend radially outward from the mounting ring.

29. (Appealed) The valve of claim 15, wherein the ring is balloon expandable.

30. (Appealed) The valve of claim 15, wherein the sleeve and cusp are formed of different materials.

31. (Appealed) The valve of claim 15, wherein the at least one cusp comprises one of a homogenic material, an allogenic material and a xenogenic material.

32. (Appealed) The valve of claim 15, wherein the at least one cusp comprises a synthetic material.

33-41. (Cancelled)

42. (Appealed) The valve device of claim 15, wherein the ring has a transport configuration for transporting the valve device to the desired location and a fasten configuration for fastening the valve device at the desired location, and comprising at least one fastener extending from the ring in a direction radially outward with respect to the sleeve when the ring is in the fasten position.

43. (Appealed) The valve device of claim 42, wherein the at least one fastener includes at least one leg having a sharpened distal end.

44. (Appealed) The valve device of claim 43, wherein the sharpened distal end is configured to pierce tissue when the valve device is in the fasten configuration at the desired location.

9. EVIDENCE APPENDIX

None

10. RELATED PROCEEDINGS APPENDIX

None